SYSTEMS AND METHODS OF 3 DIMENSIONAL ULTRASONIC IMAGING OF HARD TISSUE

This application claims priority from United States Patent application 60/344,803 filed on January 07, 2002 and from United States Patent application 60/361,091 filed on March 01, 2002

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to systems and methods of 3 dimensional ultrasonic imaging of hard tissue and, more particularly, to a system and method of imaging imperfections in bone (e.g. fractures, jount abnormalities and implanted surgical anchors.) Preferably, images produced by the system additionally contain depictions of soft tissue surrounding the bone, as part of an integrated 3D rendering.

Orthopaedic medicine has traditionally relied upon radio-graphic images (e.g. X-Ray or CT scan) of bone tissue as a means of diagnosing bone abnormalities including fractures and malformations. These methods require exposing a patient to radiation. Significant amounts of radiation are required in order to produce 3D images using these techniques. Further, the equpment required for the practice of these techniques is typically expensive and of limited portability. Ultrasound offers a promising alternative to these prior art methods of bone imaging as will be discussed below.

The concept of 3 dimensional ultrasonic imaging is not unknown. However, it has traditionally been applied to soft tissue as exemplified in this first group of prior art references.

U.S. Patent 4,100,916 issued to King describes an apparatus for collecting three-dimensional data pertaining to animal soft tissue organ structures. Teachings of King are strictly limited to soft tissue imaging and contain neither a hint nor suggestion that renderings of bone or imperfections therein may be produced by ultrasound.

U.S. Patent 4,798,210 issued to Ledley describes a method for developing a 3D image of a 3D object using ultrasound whereby a first image is combined with a second image in order to create a 3D image. Again, teachings of Ledley contain neither a hint nor suggestion that renderings of bone or imperfections therein may be produced by ultrasound.

U.S. Patent 5,924,989 issued to Polz is an additional example of a three dimensional ultrasonic system for capturing images of dynamic organs such as the heart

or other parts of the respiratory system. Like Ledley. Polz employs a combination of different images in order to complete the three dimensional image. Again, teachings of Polz contain neither a hint nor suggestion that renderings of bone or imperfections therein may be produced by ultrasound.

U.S. Patent 5,928,151 issued to Hossack et al. is a further example of a three dimensional ultrasonic scanning system. Again, teachings of this patent contain neither a hint nor suggestion that renderings of bone or imperfections therein may be produced by ultrasound. The opposite is true, the emphasis on the ability to work without contrast agents suggests that Hossack envisioned only soft tissue applications.

U.S. Patent 6,120,453 issued to Sharp is a three dimensional ultrasound system. The teachings of this patent are similar to those of Ledley and Polz. Again, Sharp employs the combination of several images to create a three dimensional image. Again, Sharp offers neither a hint nor suggestion that renderings of bone or imperfections therein may be produced by ultrasound.

In summary, none of the patents in this first group even imply that generation of 3D images of bone can be generated using ultrasound technology. Instead, they stress various means of increasing resolution of 3D images of soft tissue. Application of these methods directly to hard tissue is impractical because the echo reflection properties of soft tissue are not similar to those of hard tissue.

The concept of ultrasonic imaging of bone is also not unknown. However, bone images produced by ultrasound are typically not three dimensional as exemplified by this second group of prior art references.

U.S. Patent 4,476,873 issued to Sorenson et al. is an ultrasound scanning system used for imaging skeletal structure. This scanning system can distinguish between hard and soft tissue and is used to detect scoliosis. However, figures 14-18 of this patent make it abundantly clear that while data may be collected in three dimensions, output is supplied as graphs . Thus, it is an inherent disadvantage of Sorenson that images are not provided as a result of the scan. It follows that three dimensional images of bone are not provided. Further, Sorenson teaches differentiation between lungs containing air and bones. It will be appreciated that lung tissue, which presents alternating layers of air and soft tissue, is more different from bone than other soft tissues such as muscle. Further, Sorenson teaches that Snell's law typically causes most transmitted energy to be reflected along a line which is at

an angle to a longitudinal axis of the transmitting transducer. Therefore, Sorenson teaches extensive amplification of the small amount of reflected energy returning along this axis or, in the alternative, capture of reflected energy at one or more additional transducers. Thus, Sorenson teaches determination of co-ordinates of a point in three degrees of freedom , as opposed to six degrees of freedom. Thus changes in an angle of a surface over distance are not determined by these teachings. This is a distinct and inherent disadvantage which renders these teachings unsuitable to use in imaging long bones.

U.S. Patent 5,140,988 issued to Stouffer et al. is a method and apparatus for imaging bone structures in animal carcasses. Figures 2 and 3 of this patent demonstrate that the teachings of Stouffer relate to 2 dimensional images of bone. Thus, it is an inherent disadvantage of Stouffer that three dimensional images of bone are not provided.

U.S. Patent 5,840,029 issued to Mazess et al is a method for using ultrasound to measure bone. Mazess concers himself primareily with measurement of bone properties.Mazess contains neither a hint nor suggestion that it is feasible or desireable to generate a 3D image of a bone.

U.S. Patent 5,879,301 issued to Chibrera et al. is a method for detecting the properties of bone using ultrasound, specifically for detecting osteoporosis. It is an inherent disadvantage of Chibrera that production of images of measured bones is not taught.

U.S. Patent 6,015,383 issued to Buhler et al. teaqches acoustic analysis0 to detect the characteristics of bone tissue where the edge of the bone is detected. However, figures 3-6 of this patent make it abundantly clear that while data may be collected in three dimensions, output is supplied as graphs . Thus, it is an inherent disadvantage of Buhler that images are not provided as a result of the scan. It follows that three dimensional images of bone are not provided.

U.S. Patent 322,507 issued to Passi et al. is an ultrasonic system for evaluation bone tissue. Like other patents in this group, it has the inherent disadvantage of providing output as graphs rather than images. Further, measurements according to these teachings are of acoustic properties and not of surfcae position co-ordinates.

Thus, while members of this second group of patents teach assays of bone using ultrasound technology, they fail to teach production of a three dimensional image of a long bone.

Additional patents dealing with ultrasonic imaging of bone are summarized hereinbelow.

U.S. Patent 5,305,752 issued to Spivey is a system for imaging tissue in the body using acoustic waves. While Spivey teaches formation of a single ultrasonic image depicting both soft tissue and bone, the image is a cross-sectional image (i.e. 2 dimensional). Further, independent claim 1 of Spivey teaches dispersing a plurality of closely spaced acoustic signal detection means around a sample to be imaged. This is an additional distinct and inherent disadvantage of the teachings of Spivey.

U.S. Patent 5,465,722 issued to Fort et al. relates to a 3D ultrasonic system. Although these teachings included production of a 3D image of a bone (Figure 13), production of this image requires receiving reflected acoustic energy at a plurality of locations as optionally taught by Sorenson. Further, Fort teaches transmitting energy from a first set of locations and receiving energy at a second set of locations. This teaching specifically excludes use of specular reflection. These teachings are difficult to implement because of the complexity in processing the received signal and differentiating between soft tissue and hard tissue reflection.

U.S. Patent 6,375,616 issued to Soferman et al. is a method for determining fetal weight in utero. Although Soferman teaches application of grey level threshold in order to isolate bones from other tissue in an image, his teachings do not include use of specular reflection to form the image. In contrast, these teachings seem to include gatering of reflected energy from a single transmission at a plurality of points (column 10 lines 1-30). Reference to " E.J. Feleppa et al., Two Dimensional and Three-Dimensional Tissue-Type Imaging of the Prostate Based on Ultrasonic Spectrum Analysis and Neural-Network Classification". Suggests that Soferman is aware of the fact that fetal bone, because it is not a specular reflector, is actually more similar to soft tissue than to fully calcified bone. Therefore, direct application of the teachings of. This is a distinct and inherent disadvantage which would make transfer of these teachings to imaging of adult bone problematic.

U.S. Patent 6,390,982 issued to Bova et al. is a method of creating a three dimensional image. The teachings of Bova are directed to ultrasonic probes as an adjunct to a second imaging technology in localizing bone. This means that generation of the three dimensional image from ultrasound image data alone is beyond the scope of Bova's teachings. This is a distinct and inherent disadvantage. Further these teachings rely upon a

probe as taught in U.S. Patent 5,893,832 to Song which relies upon collection of data at a plurality of points dispersed radially about an axis of a beam of transmitted energy.

U.S. Patent 6,413,215 issued to Wu et al. is an ultrasonic system for detecting the wear of artificial joints. The teachings of Wu rely upon scattering of ultrasonic energy as a result of cavitation events in synovial fluid. Further, Wu teaches output of data as particle size information, not particle position. In summary, these teachings have little relevance to the instant application because cavitation events are not expected to occur in typical measurement of hard tissue such as bone.

There is thus a widely recognized need for, and it would be highly advantageous to have, a system and method of 3 dimensional ultrasonic imaging of hard tissue devoid of the above limitations.

SUMMARY OF THE INVENTION

According to one aspect of the present invention there is provided a method of creating an ultrasonic image of a hard tissue within a target. The method includes: (a) transmitting from at least one ultrasonic transducer at a defined location a focused beam of ultrasonic energy towards the target; (b) adjusting an angle of incidence between the focused beam and a surface of the hard tissue to a normal angle, by positioning the at least one ultrasonic transducer; (c) receiving a significant portion of the energy as an echo-reflection at the defined location; (d) defining the location of the transducer in six degrees of freedom; (e) calculating a set of position co-ordinates for a portion of a surface causing the echo-reflection; (f) moving the ultrasonic transducer to a different defined location; (g) repeating steps a through f; and (h) compiling at least a portion of the sets of position co-ordinates to generate a map of at least a portion of the surface causing the echo-reflection; (i) determining at least a portion of the map which represents a surface of the hard tissue within the target according to a predetermined rule.

According to another aspect of the present invention there is provided a system for creating an ultrasonic image of a hard tissue within a target. The system includes: (a) at least one ultrasonic transducer positioned at a defined location and capable of transmitting a focused beam of ultrasonic energy towards the target and of receiving a significant portion of the energy as an echo-reflection from a surface of the hard tissue and of communication

with a central processing unit; (b) a position locator and adjustment mechanism coupled to the at least one transducer and designed and constructed to be capable of adjusting an angle of incidence between the focused beam and the surface of the hard tissue in response to a command from the central processing unit and to be capable of defining the location of the transducer in six degrees of freedom and transmitting the definition to the central processing unit as well as to be capable of moving the ultrasonic transducer to a series of different defined location; (c) the central processing unit designed and configured to transmit commands to the position locator and adjustment mechanism to cause the transducer to move to the series of different defined locations, to calculate a set of position co-ordinates for at least a portion of the surface of the hard tissue causing the echo-reflection and to compile a plurality of the sets of position co-ordinates to generate a map of at least a portion of the surface of the hard tissue by applying a predetermined rule.

According to yet another aspect of the present invention there is provided a method of creating an ultrasonic image of a hard tissue including irregularities thereupon, the method includes:

(a) transmitting a focused beam of ultrasonic energy from at least one ultrasonic transducer at a first defined location towards a surface of the hard tissue; (b) receiving a portion of the energy as an echo-reflection at at least one second defined location; (c) calculating a set of position co-ordinates corresponding to an ultrasonic reflector for each of the at least one second defined location; (d) repeating steps a through c; (e) deciding if the reflector is a hard tissue according to a first predetermined criteria; (f) deciding if the reflector is an irregularity on the surface of hard tissue according to a second predetermined criteria; and (g) compiling at least a portion of the sets of position co-ordinates to generate a map of at least a portion of the surface of the hard tissue.

According to still another aspect of the present invention there is provided a system for creating an ultrasonic image of a hard tissue and any irregularities thereupon within a target. The system includes: (a) at least one ultrasonic transmitter capable of transmitting a focused beam of ultrasonic energy from at least one first defined location towards a surface of the hard tissue and further capable of communication with a central processing unit; (b) at least one ultrasonic receiver capable of receiving a portion of the energy as an echo-reflection at at least one second defined location and further capable of communication with the central processing unit; (c) a position locator and adjustment

mechanism operably connectable to the at least one transmitter and the at least one receiver and capable of communication with the central processing unit and designed and constructed to be capable of moving the transmitter and the receiver to a series of different defined locations; and (d) the central processing unit. The central processing unit is designed and configured to: (i) calculate a set of position co-ordinates corresponding to an ultrasonic reflector for each of the at least one second defined location; (ii) decide if the reflector is a hard tissue according to a first predetermined criteria; (iii) decide if the reflector constitutes an irregularity on the surface of the hard tissue according to a second predetermined criteria; (iv) compile at least a portion of the sets of position co-ordinates to generate a map of at least a portion of the surface of the hard tissue; and (v) transmit commands to the position locator and adjustment mechanism to cause the transducer to move to the series of different defined locations.

According to further features in preferred embodiments of the invention described below, controlling includes at least one item selected from the group consisting of the adjusting and the moving.

According to still further features in the described preferred embodiments at least one item selected from the group consisting of the adjusting and the moving is performed manually by a practitioner of the method.

According to still further features in the described preferred embodiments performed manually indicates at least one manual input selected from the group consisting of a manual position adjustment by the practitioner of the method and at least one instruction transmitted to the central processing unit by the practitioner of the method.

According to still further features in the described preferred embodiments the angle of incidence is a normal angle determined by moving the at least one ultrasonic transducer.

According to still further features in the described preferred embodiments each of the defined locations is defined as a set of position co-ordinates.

According to still further features in the described preferred embodiments each first defined location includes at least one angle of transmission as part of its definition.

According to still further features in the described preferred embodiments the method further includes employing additional first defined locations for the transmitting.

Additional first defined locations include, but are not limited to, transmitting in additional directions (i.e. at different angles) from a single defined location.

According to still further features in the described preferred embodiments the method further includes employing additional second defined locations for the receiving.

According to still further features in the described preferred embodiments the method the controlling includes repositioning at least one item selected from the group consisting of at least one of the at least one ultrasonic transducer and an ultrasonic receiver.

According to still further features in the described preferred embodiments the predetermined rule is selected from a group consisting of a geometric rule and a physical rule. A combination including a geometric rule and/or a physical rule is therefore included.

According to still further features in the described preferred embodiments the predetermined rule includes maximization of the function:

$$F(x,y, r1. r2, r3) = \Sigma (refl(Area 1)) - C^* \Sigma (ref2(Area 2))$$

wherein (x ,y) represent an assumed position coordinate within a slice of the hard tissue within the target; and

wherein r1,r2 and r3 each individually represent a radius of the hard tissue with respect to the assumed position co-ordinate at a series of angles $\alpha 1$, $\alpha 2$ and $\alpha 3$respectively;

wherein refl represents a sum of the portion of energy received as an echo reflection within a first area (Area 1) and ref2 represents a sum of the portion of energy received as an echo reflection within a second area (Area 2); and wherein C represents a constant.

According to still further features in the described preferred embodiments the method further includes controlling, by means of a central processing unit, performance of at least a portion of the method.

According to still further features in the described preferred embodiments controlling indicates at least one control mechanism selected from the group consisting of mechanical control, selection from an array and electronic control.

According to still further features in the described preferred embodiments the position locator and adjustment mechanism employs at least one type of control selected

from the group consisting of mechanical control, selection from an array and electronic control.

According to still further features in the described preferred embodiments the position locator and adjustment mechanism is further designed and configured to receive input from an operator of the system, the input being selected from the group consisting of a manual position adjustment by an operator of the system and at least one instruction transmitted to the central processing unit.

According to still further features in the described preferred embodiments at least one item selected from the group consisting of data pertaining to the echo-reflection, the set of position co-ordinates for a portion of the surface of the hard tissue causing the echo-reflection and at least a portion of the map is displayed upon a display device.

According to still further features in the described preferred embodiments the map is selected from the group consisting of a two dimensional map and a three dimensional map.

The present invention successfully addresses the shortcomings of the presently known configurations by providing systems and methods of 3 dimensional ultrasonic imaging of hard tissue and/or imperfections contained therein (e.g. fractures, jount abnormalities and implanted surgical anchors.) Preferably, images produced by the system additionally contain depictions of soft tissue surrounding the bone, as part of an integrated 3D rendering.

Implementation of the method and system of the present invention involves performing or completing selected tasks or steps manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of preferred embodiments of the method and system of the present invention, several selected steps could be implemented by hardware or by software on any operating system of any firmware or a combination thereof. For example, as hardware, selected steps of the invention could be implemented as a chip or a circuit. As software, selected steps of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In any case, selected steps of the method and system of the invention could be described as being performed by a data processor, such as a computing platform for executing a plurality of instructions.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

FIG. 1 is a simplified flow diagram illustrating a sequence of events involved in performance of a method according to the present invention.

FIG. 2 is a schematic representation of components of a system according to the present invention.

FIG. 3 is a simplified flow diagram illustrating a sequence of events involved in performance of an additional method according to the present invention.

FIG. 4 is a schematic representation of components of an additional system according to the present invention.

FIGs. 5 a-c illustrate possible arrangements of ultrasonic transducers with respect to a target according to the present invention.

FIGs. 6 a and b present maps produced by the present invention.

FIG. 7 is a diagram illustrating the physical relationship among variables in a formula presented in support of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of systems and methods of ultrasonic imaging of hard tissue which can be used to produce 3 dimensional maps or images of hard tissue surfaces and/or irregularities thereupon.

Specifically, the present invention can be used to image imperfections in bone (e.g. fractures, jount abnormalities and implanted surgical anchors.) Preferably, images produced by the present invention additionally contain depictions of soft tissue surrounding the bone, as part of an integrated 3D rendering.

The principles and operation of systems and methods according to the present invention may be better understood with reference to the drawings and accompanying descriptions.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

The present invention is embodied by a method **20** (figure 1) of creating an ultrasonic image **48** of a hard tissue **70** (figure 2) within a target **68**.

For purposes of this specification and the accompanying claims, the term "ultrasonic" pertains to sound waves with a frequency in excess of approximatelt 20 kHz, more preferably in the range of 1 mHz to 20 mHz.

For purposes of this specification and the accompanying claims, the term "hard tissue" includes, but is not limited to bone such as cortical bone or trebicular bone. Bone refers to calcified fully developed bone capable of generating an ultrasonic echo-reflection in approximate accordance with Snell's law. While a developing fetus may have bones, these fetal bones are excluded from the definition of hard tissue because they are primarily cartilaginous, significant calcification typically taking place well after parturition.

The term "target" as used in this specification and the accompanying claims indicates any portion of a subject which may be under examination.

Method **20** includes transmitting **22** from at least one ultrasonic transducer **62** at a defined location **64** a focused beam **66** of ultrasonic energy towards target **68**. Preferably, beam **66** is pulsed.

For purposes of this specification and the accompanying claims, the term "focused" means that a majority of transmitted energy is concentrated within a defined area surrounding an axis of a transmitted beam. Focusing may be caused by interference of a plurality of transmitted beams. Depending upon the arrangement of transmitting transducers **62** (see figures 5a-c) , this interference may involve a temporal component (i.e. transducers located further from the target transmitting earlier, those located closer to the target transmitting later) as well as a spatial component.

For purposes of this specification and the accompanying claims, the term "beam" indicates a ray of energy transmitted from one or more sources.

For purposes of this specification and the accompanying claims, the term "pulsed" means temporally defined.

Method **20** further includes adjusting **24** an angle of incidence between focused beam **66** and a surface **69** of the hard tissue **70** to a normal angle, by positioning the at least one ultrasonic transducer **62**.

For purposes of this specification and the accompanying claims, the term "normal angle" refers to an angle at which a single ultrasonic transducer at a fixed location can transmit energy and receive an echo reflection of a significant portion of the transmitted energy. In theory a normal angle is 0° (zero degrees), and a 0° angle is always optimal. In practice the range of normal angles is a function of surface properties of the hard tissue under examination so that 0° $\pm$ 15°, more preferably 0 ° $\pm$ 10°, most preferably 0° $\pm$ 5 °, is functionally normal for purposes of generating a measurable echo reflection.

Method **20** further includes receiving **26** a significant portion **65** of the energy as an echo-reflection at defined location **64**. Method **20** further includes defining **30** location **64** of transducer **62** in six degrees of freedom.

Method **20** further includes calculating **32** a set of position co-ordinates **46** for a portion of a surface causing the echo-reflection. Method **20** further includes moving **34** ultrasonic transducer **62** to a different defined location **64**, and repeating **36** transmitting **22**,

adjusting **24**, receiving **26**, defining **30**, calculating **32** and moving **34**. Repeating **36** is preferably performed many times.

Method **20** further includes compiling **38** at least a portion of the sets of position co-ordinates **46** to generate a map **48** of at least a portion of surface **69** causing echo-reflection **65**.

Method **20** further includes determining **40** at least a portion of map **48** which represents surface **69** of hard tissue **70** within target **68** according to a predetermined rule.

Optionally, but preferably, a computerized controller **72** is employed to control at leasat a portion method **20**, for example adjusting **24** or moving **34**. Computerized controller **72** may be, for example, a computer such as a personal computer (PC) having an operating system such as DOS, Windows^{TM}, OS/2^{TM} or Linux; Macintosh^{TM}, Palm OS ^{TM}, an EPOC^{TM} computer; a computer having JAVA^{TM} -OS as the operating system; a graphical workstations such as a computer of Sun Microsystems^{TM} or Silicon Graphics^{TM}, or another computer having some version of the UNIX operating system such as AIX^{TM} or SOLARIS^{TM} of Sun Microsystems^{TM}; or any other known and available operating system, or a personal digital assistant (PDA), each of which is known to include an inherent or connectable display device**82**.

Optionally, but also preferably, adjusting **24** and/or moving **34** may be performed manually by a practitioner of method **20**. Manually, as used herein, indicates at least one manual input. A manual input may be, for example, a manual position adjustment by the practitioner of method **20** or at least one instruction transmitted to the central processing unit **72** by the practitioner of method **20** (e.g. via input device **84**). Input device **84** may be any device for entry of data to a computing device. Therefore, input device **84** may include, but is not limited to, a keyboard, a computer mouse, a trackpad, a track ball, a stylus, a touchscreen and a microphone.

Practice of method **20** typically involves use of a system **60** which further embodies the prsent invention. System **60** creates an ultrasonic image of hard tissue **70** within target **68**.

System **60** includes at least one ultrasonic transducer **62** positioned at defined location **64** and capable of transmitting **22** focused beam **66** of ultrasonic energy towards target **68** and of receiving **26** significant portion **65** of the energy as an echo-reflection from

surface **69** of hard tissue **70** and of communication with central processing unit **72.** Preferably the angle of incidence between beam **66** and surface **69** of hard tissue **70** is a normal angle determined by moving transducer **62** so that echo reflection **65** is maximized.

System **60** further includes a position locator and adjustment mechanism **74** coupled to at least one transducer **62** and designed and constructed to be capable of adjusting **24** an angle of incidence between focused beam **66** and surface **69** of hard tissue **70** in response to a command from central processing unit **72.** Position locator and adjustment mechanism **74** is further capable of defining **30** location **64** of transducer **62** in six degrees of freedom. Position locator and adjustment mechanism **74** is further capable of transmitting the definition to central processing unit **72.** Position locator and adjustment mechanism **74** is further capable of moving ultrasonic transducer **62** to a series of different defined locations **64.**

System **60** further includes central processing unit **72** designed and configured to transmit commands to position locator and adjustment mechanism **74** to cause transducer **62** to move to a series of different defined locations **64.** Central processing unit **72** is further designed and configured to to calculate position co-ordinates **46** for at least a portion of surface **69** of hard tissue **70** causing echo-reflection **65** and to compile a plurality position co-ordinates **46** to generate map **48** of at least a portion of surface **69** of hard tissue **70** by applying a predetermined rule.

Preferably the predetermined rule employed by CPU **72** in determining **40** map **48** representing surface **69** of hard tissue **70** includes a geometric rule or a physical rule or a combination thereof.

Maximization of the function :

$F(x,y, r1. r2, r3) = \Sigma\ (refl(Area\ 1)) - C^*\Sigma\ (ref2(Area\ 2))$ (see figure 7)

is presented as a non limiting example of a predetermined rule suited for use in the context of the present invention

According to this function:

(x ,y) represent an assumed position coordinate within a slice of hard tissue 70 within target **68**; and

r1,r2 and r3 (**103, 105** and **107** respectively) each individually represent a radius of hard tissue **70** with respect to (x,y) at a series of angles $\alpha 1$, $\alpha 2$ and $\alpha 3$respectively (**109, 111** and **113** respectively); and

refl represents a sum of the portion of energy received as echo reflection **65** within a first area (Area 1; **99**) and ref2 represents a sum of the portion of energy received as echo reflection **65** within a second area (Area 2 **101**); and

C represents a constant.

Figures 6 a and b are images of surface **69** of hard tissue **70** produced using maximization of this function.

The present invention is further embodied by an additional method **90** of creating an ultrasonic image of a hard tissue including irregularities thereupon. Method **90** includes transmitting **92** (figure 3) a focused beam **66** (figure 4) of ultrasonic energy from at least one ultrasonic transducer, pictured here as transmitter **59** for clarity, at a first defined location **64** towards a surface **69** of hard tissue **70**.

Method **90** further includes receiving **94** a portion **65** of the energy as an echo-reflection at at least one second defined location **63**. The nature of surface **69** will determine the number of locations **63** (and receivers **61**) which are optimal. In practice, both receiver **61** and transmitter **59** will usually both be transducers **62**, although this is not always the case.

Method **90** further includes calculating **96** a set of position co-ordinates **46** corresponding to an ultrasonic reflector for each second defined location **63** at which energy **65** is received.

Method **90** further includes repeating transmitting **92**, receiving **94** and calculating **96**.

Method **90** further includes deciding **100** if the reflector is a hard tissue according to a first predetermined criteria and deciding **102** if the reflector is an irregularity on the surface of hard tissue according to a second predetermined criteria.

The first predetermined criteria may be, for example, definition of a small area upon which echo reflection **65** is distributed. Confineminemt of reflection **65** to defined small area indicates that it is caused by a hard surface.

The second predetermined criteria may be, for example, definition of a larger area upon which echo reflection **65** is distributed. Dispersal of reflection **65** to a larger area indicates that it is caused by an irregularity.

Alternately, or additionally, first and second predetermined criteria may include analysis of the geometry of the area in which reflection **65** is received by geometrical properties of the area

Method **90** further includes compiling **104** at least a portion of the sets of position co-ordinates **46** to generate map **48** of at least a portion of surface **69** of hard tissue **70.**

Thus, determination of a position co-ordinate **46** is preferably accomplished by comparing received energy **65** at position **63** with transmitted energy **66**. In order to make this determination, the positions of transmission origin **64** and receiver position **63** relative to one another must be known. Alternately, but also preferably, determination of a position co-ordinate **46** is accomplished by analyzing the pattern of energy **65** received **94** at many. Thus it is often useful to employ arrays of transducers **62** in systems **60** or **160** (figure 4) as pictured in figures 5 a-c in order to quickly gather data required for performance of methods **90** and/or **20.**

Performance of methods **90** and/or **20** is most efficient when each of defined locations **64** and **63** is defined as a set of position co-ordinates. Preferably, each first defined location **64** includes at least one angle of transmission as part of its definition.

Preferably method (**20** or **90**) further includes employing additional first defined locations **64** for transmitting (**22**; **92**). Additional first defined locations **64** include, but are not limited to, transmitting in additional directions (i.e. at different angles) from a single defined location **64**. Preferably method **90** further includes employing additional second defined locations **93** for receiving **94**. Arrays of transducers **62** as shown in figures 5a through c are useful in this respect as they increase the speed at which position co-ordinates **46** may be generated by increasing the speed at which transmission/reception from a large number of locations may be accomplished.

In association with methods **20** and **90.** controlling may include repositioning transducer **62,** transmitter **59** or ultrasonic receiver **61,** whether by means of choosing an additional item from an array or by physically moving an item .

Methods **20** and/or **90** are both amenable to controlling, by means of a central processing unit, performance of at least a portion of the method. This automated control enhances the speed and performance of **20** and/or **90.** Controlling may indicate, for example, use of a control mechanism such as mechanical controller, selection from an array, electronic control or combinations including any of same.

System **160** for creating an ultrasonic image of a hard tissue and any irregularities thereupon within a target is depicted in figure 4. System **160** includes at least one ultrasonic transmitter **59** capable of transmitting **92** beam **66** from at defined location **64** towards surface **69** of hard tissue **70** and further capable of communication with central processing unit 72.

System **160** further includes ultrasonic receiver **61** capable of receiving **94** a portion **65** of the energy as an echo-reflection at second defined location **63** and further capable of communication with central processing unit 72.

System **160** further includes a position locator and adjustment mechanism **74** operably connectable to transmitter **59** and receiver **61** and capable of communication with central processing unit 72. Position locator and adjustment mechanism **74** is designed and constructed to be capable of moving transmitter **59** and receiver **61** to a series of different defined locations (64; 63). Position locator and adjustment mechanism **74** may employs, for example, a mechanical control mechanism, selection from an array or an electronic control mechanism.

Position locator and adjustment mechanism **74** is optionally, but preferably, designed and configured to receive input from an operator of the system **(60; 160)**. The input may be, for example, a manual position adjustment by an operator of the system or at least one instruction transmitted to central processing unit 72 (e.g. by data input device **84**).

System **160** further includes central processing unit **72** designed and configured to calculate **96** a set of position co-ordinates **46** corresponding to an ultrasonic reflector for each second defined location **63**. Central processing unit **72** is further designed and configured to decide **100** if the reflector is a hard tissue according to a first predetermined criteria. Central processing unit **72** is further designed and configured to decide **102** if the reflector constitutes an irregularity on the surface of the hard tissue according to a second predetermined criteria. Central processing unit **72** is further designed and configured to compile **104** at least a portion of the sets of position co-ordinates **46** to generate a map **48** of at least a portion of the surface of the hard tissue. Central processing unit **72** is further designed and configured to transmit commands (e.g. control **114**) to the position locator and adjustment mechanism to cause the transducers (59; **61**) to move to different defined locations (**64; 63**) .

Preferably transmitting **92** and receiving **94** occur in a single plane **75** and transmitting **92** of beam **66** is at a normal angle with repect to plane **75.**

Practice of methods **20** and **90** typically includes display **42** of output on display device **82**. Display device **82** may include any device which visually presents data to a user. Therefore, display device **82** may be, for example, a cathode ray tube display screen, a liquid crystal display, a print out , a plasma screen or an array of light emitting diodes. Similarly, systems **60** and **160** preferably include such display device **82**. Displayed output may include, but is not limited to data **44** pertaining to echo-reflection **65**, position co-ordinates **46** for a portion of surface **69** of hard tissue **70** causing echo-reflection **65**; and at least a portion of map **48** (e.g. figures 6a and 6b). Preferably, surface **69** of hard tissue **70** is visually highlighted (figure 6b). Map **48** may be presented as a two dimensional map or a three dimensional map. Preferably surface irregularities **56** are also displayed. More preferably, soft tissue of target **68** is further displayed.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.